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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,154	09/20/2005	Margaretha Grind	ASZD-P01-022	1056

9629 7590 09/06/2006

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EXAMINER	
KHANNA, HEMANT	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/550,154	GRIND, MARGARETHA	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of claims 14, 16, and 18-21 that belong to Group I in the reply filed on August 11, 2006 is acknowledged.

Claims 14, 16, and 18-21 are pending.

Claims 22-27, 30-41, 45-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 11, 2006.

Specification

2. The disclosure is objected to because of the following informalities: reference to the drawings in the heading "Brief Description of the Drawings" in the accompanying disclosure is lacking. See 37 CFR 1.74. Appropriate correction is required.

Claim Objections

3. Claim 18 is objected to because of the following informalities: the annotation of "Cgl", "Aze", "Pab" in the prodrug is unclear. For the benefit of clarity, Applicant is asked to define explicitly the annotations recited in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 14, 16, and 18-21 rejected under 35 U.S.C. 102(b) as being anticipated by Gustafsson D. (WO 02/36157).

The claims are drawn to a method of administering melagatran and prodrugs thereof to a patient in need of cholesterol-lowering therapy.

Gustafsson D. teach the administration of melagatran, pharmaceutical derivatives thereof, and prodrugs of melagatran for the manufacture of a medicament for the treatment of ischemic disorders in patients having or at risk of atrial fibrillation (abstract). In the absence of an explicitly defined patient population receiving treatment and to the extent that the Applicant defines the patient population as any population that benefits from the modification of the serum profiles of total cholesterol, lipids, lipoproteins or apolipoproteins (page 6, lines 6-10), the population of patients taught by Gustafsson D. is encompassed within the population of patients who will benefit from the modification of their serum cholesterol levels, thus meeting the limitations of the patient population in claims 14 and 16. Gustafsson D. teach that the prodrugs of melagatran include those encompassed by the formula R^1O_2C-CH_2-(R)Cgl-Aze-Pab-OH, wherein R^1 represents C_{1-10} alkyl or benzyl, such as a linear or branched C_{1-6} alkyl, and the OH group replaces one of the amidino hydrogens in Pab (page 4, lines 15-20). Further, Gustafsson D. teach that while melagatran and derivatives are best delivered parenterally in admixture with a pharmaceutically-acceptable adjuvant, the prodrugs of

melagatran are best administered orally (page 6, lines 25-30), thus meeting the limitations of claim 18-19. Additionally, Gustafsson D. teach suitable doses of melagatran, prodrugs and derivatives thereof which include those in the range 0.1 mg once daily to 25 mg three times daily, and/or up to 100 mg infused parenterally over a 24 hour period, for melagatran, and in the range of 0.1 mg once daily to 100 mg three times daily (e.g. 10 to 100 mg twice daily, such as 36 mg twice daily or thereabouts) for prodrugs of melagatran (page 9, lines 1-5). Gustafsson D. also teach a clinical trial to demonstrate the tolerability of different doses of a melagatran prodrug represented by the formula R^1O_2C-CH_2-(R)Cgl-Aze-Pab-OH, wherein R^1 is ethyl in a patient population with a history of atrial fibrillation and coronary heart disease (page 11, lines 1-20).

To the extent that the Applicant utilized the same patient population to observe for modifications in cholesterol, triglycerides, and LDL serum concentrations in the large-scale Phase III clinical trial, as was utilized by Gustafsson D. (mentioned above), and based on Applicant's admittance that the instant clinical trial protocol was similar in both dosage, compound and patient population, the teachings of Gustaffson D. will inherently result in the claimed method of cholesterol-lowering. Sufficient evidence of similarity is deemed to be present between the method of Gustaffson D. and the Applicant's claimed method to shift the burden to the Applicant to provide evidence that the claimed method is unobviously different than that of Gustaffson D.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hemant Khanna Ph.D.
August 28, 2006

ANISH GUPTA
PRIMARY EXAMINER